UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 28, 1999

MEMORANDUM

SUBJECT: OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT UPDATING THE COUMAPHOS RED PUBLISHED AUGUST 1996. (PC 036501 and DP Barcode D262059)

FROM: Renee Sandvig, Environmental Protection Specialist
Reregistration Branch II
Health Effects Division (7509C)

TO: Christina Jarvis, Risk Assessor
Reregistration Branch II
Health Effects Division (7509C)

THRU: Al Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

Please find attached an occupational exposure and risk assessment for the use of coumaphos.

DB Barcode: D262059

Pesticide Chemical Codes: 036501

EPA Reg Nos: 606-105, 960-169, 960-184, 2393-378, 2393-385, 11556-4, 1556-11, 11556-14, 1155-20, 11556-21, 11556-23, 11556-98, 11556-115, 28293-88, 28293-91, 28293-122, 34704-267, 34704-306, and 67517-21.

EPA MRID No.: 442529-01 and 442529-02

PHED: Yes, Version 1.1

Executive Summary

Coumaphos, (0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate) is an organophosphorus acaricide. It is applied directly to animals, including dairy cattle, beef cattle, swine, and horses, for the control of arthropod pests including: ticks, scabie mites, lice, flies (including face flies and horn flies), fleece worms, and screw worms.. The solid technical is 96 percent active ingredient (ai), other formulations include a dust formulation intermediate (25 percent ai), a dust (1 percent ai), an emulsifiable concentrate (6.15 and 11.6 percent ai), and a flowable concentrate (42 percent ai). Multiple applications to livestock and/or livestock areas are permitted by current labels.

Coumaphos can be applied with high and low pressure hand wands, dip vats, mechanical dusters, shaker cans, dust bags, and back oilers/rubbers. Depending on animals treated and formulation type, the maximum label application rates range from 0.005 to 0.025 pounds active ingredient per gallon for sprays or dips, 0.076 lbs active ingredient per gallon of oil for backrubbers, 0.000625 to 0.013 lbs ai per animal for dust application, and 0.042 lbs ai per 1000 square feet of swine bedding treatment[1]. There are no registered uses of coumaphos on agricultural crops or in/around residences.

All exposure scenarios, except for mixing/loading liquids for dip vat use on cattle, will be short-term exposure duration only (less than seven days). Most of the non dip vat application of coumaphos is done by a farmer to his own animals, when arthropod pests become a problem. Cattle dip vat use is also considered an intermediate-term exposure (seven days to several months) since the quarantine area dip vats in Texas along the Mexican border are staffed on a continual basis as opposed to a farmer just dipping the animals that are on his farm. Mixing and loading liquids for cattle dip vat use may not be considered a chronic exposure since the USDA workers dip only the local US cattle and are removed from dipping operations if their cholinesterase levels reach a level of concern. The routes of exposure are dermal and inhalation.

The Pesticide Handler Exposure Database (PHED) unit exposure data was used where applicable and study data was used for dermal applicator exposure to dip vats, shaker cans and mechanical dusters. There was no data available to assess several exposure scenarios, most of them using the dust formulation.

The target MOEs for occupational workers are 100 for dermal and 300 inhalation risk. The effects seen at both short-term dermal and inhalation LOAELs were cholinesterase inhibition; therefore, the MOEs were combined to identify an aggregate risk index (ARI). An ARI was used since the target MOE values for inhalation and dermal exposure were different. The effects seen at both intermediate-term dermal and inhalation LOAELs were cholinesterase inhibition, so the MOEs were combined to identify an ARI also. Chronic endpoints were not selected because coumaphos may not be considered to have exposures of chronic durations.

Based on the use patterns of coumaphos, 9 major exposure scenarios were identified: (1a) mixing/loading liquids for high pressure hand wand; (1b) mixing/loading liquids for hydraulic type dip vats; (1c) mixing/loading liquids for swim type dip vats; (1d) mixing/loading liquids for back rubber/oilers; (2) loading dust into bags; (3) applying liquids with a high pressure hand wand; (4) applying dusts with a shaker can; (5) mixing/loading/applying liquids for low pressure handwand; and (6) loading/applying dusts with a mechanical duster. Exposure to the applicator from dip vats use was because there was no data to assess the exposure scenario.

Calculations of risk based on combined dermal and inhalation exposure indicate that the ARIs are **more than** **<u>1</u>** or that the dermal only MOEs are **more than** **<u>100</u>** with maximum risk reduction measures for all of the short and intermediate term occupational exposure scenarios listed above **except** for the following scenarios: applying liquids with a high pressure handwand at the application rate for cattle and swine and use rate of 1000 gallons/day, applying dusts with a shaker can at the rate for cattle, horses and swine bedding, and applying dusts with a mechanical duster at the rate for cattle, horses and swine bedding.

No registered uses of coumaphos fall under the Worker Protection Standard (WPS). The EPA has established the following statement for all non WPS occupational uses of coumaphos end use products, "Do not contact treated animals until sprays have dried and dusts have settled on the coat."

HED has determined that there is likely to be minimal exposure to people contacting treated animals immediately after application is complete. No exposure data are available to assess risk from such contact. HED has determined that the amount of exposure is likely to be substantially lower than the exposure to handlers; therefore, post application exposure was not assessed.

OCCUPATIONAL EXPOSURE AND RISK ASSESSMENT FOR THE USE OF COUMAPHOS.

This document is an update on the Coumaphos RED written August 1996. It is for use in EPA's development of the Coumaphos Reregistration Eligibility Decision Document (RED), HED presents the results of its occupational exposure and risk assessment.

Use Patterns

Coumaphos (0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate) is an organophosphorus acaricide. It is applied directly to animals, including dairy cattle, beef cattle, swine, and horses, for the control of arthropod pests including: ticks, scabie mites, lice, flies (including face flies and horn flies), fleece worms, and screw worms. The solid technical is 96 percent active ingredient (ai), other formulations include a dust formulation intermediate (25 percent ai), a dust (1 percent ai), an emulsifiable concentrate (6.15 and 11.6 percent ai), and a flowable concentrate (42 percent ai). Multiple applications to livestock and/or livestock areas are permitted by current labels.[1]

Coumaphos can be applied with high and low pressure hand wands, dip vats, mechanical dusters, shaker cans, dust bags, and back oilers/rubbers. Depending on animals treated and formulation type, the maximum label application rates range from 0.005 to 0.025 pounds active ingredient per gallon for sprays or dips, 0.076 lbs active ingredient per gallon of oil for backrubbers, 0.000625 to 0.013 lbs ai per animal for dust application, and 0.042 lbs ai per 1000 square feet of swine bedding treatment[1]. The majority of coumaphos is used on beef cattle. There are no registered uses of coumaphos on agricultural crops or in/around residences.

A *Livestock Spraying Practices Survey* was conducted in July of 1996[2] and there were 332 responses from 2000 surveys mailed to cow producers, with 74 of the respondents stating that they do spray livestock for fly control. Of the respondents, the average herd size is 186, with 34 percent having from 1 to 99 cows, 45.5 percent having 100 to 499, and 8 percent having 500 or greater cattle. The following data is from the 74 respondents who spray cattle for fly control. The average number of cattle sprayed per day is 135, with 18 percent spraying less than 50 and 29 percent spraying from 50 to 99 cattle per day. The survey also states that 93 percent of the respondents involve only one to two people in their spray operations. The average number of hours an individual sprays in one day is 2.2, with 45 percent spraying one hour or less, 26 percent spraying two hours, and 29 percent spraying more than two hours per day and the average number of times per year an individual sprays is 3.4, with 95 percent spraying 7 days or less per year.[2]

As reported in the USDA's <u>Agriculture Statistics 1997</u> , there are on average 85 beef cattle per farm with 31 percent of farms having less than 50 cattle, 19 percent of farms having 50 to 99 cattle, 36 percent of farms having 100 to 499 cattle and 14 percent of farms having over 500 cattle.. There are on average 122 dairy cows per farm with 16 percent of farms having less than 50 dairy cattle, 27 percent of farms with 50 to 99 dairy cattle, and 57 percent of farms with more than 100 dairy cattle. There are on average 357 pigs per farm with 60 percent of farms having less than 100 pigs, 23 percent of farms with 100 to 499 pigs, 17 percent of farms with more than 500 pigs. On average there are 140 sheep per farm (no range data were provided). All data is from farms in the United States.[3]

According to the US Department of Commerce's 1992 Census of Agriculture, there are, on average, 77 beef cattle per farm with 80 percent of farms with less than 50 cattle, 19 percent of farms with 100 to 499 cattle and 1 percent of farms with more than 500 cattle. There are, on average, 128 dairy cattle per farms with 60 percent of farms with less than 50 dairy cattle, 27 percent of farms with 50 to 99 dairy cattle, and 13 percent of farms with more than 500 dairy cattle. There are, on average, 301 pigs per farm with 43 percent of farms with less than 50 pigs, 41 percent of farms with 50 to 499 pigs, and 16 percent of farms with more than 500 pigs. There are, on average, 133 sheep per farm, with 50 percent of farms with less than 24 sheep, 33 percent of farms with 25 to 99 sheep and 17 percent of farms with more than 100 sheep. There are, on average, 86 horses and 53 goats per farm (no range data were provided). All data is from farms in the United States.[4]

Between 500,000 to 1.3 million cattle are treated in dip vats with coumaphos in Mexico and transported across the Texas/Mexican border every year. The dipping in Mexico is supervised by US federal workers. The United States Department of Agriculture (USDA) uses coumaphos in dip vats, located principally in Texas along Mexican border, to control ticks that come into the US from infested areas in Mexico and carry equine and bovine piroplasmosis (Texas Cattle Fever). Livestock , almost exclusively beef cattle, from the farms in the infested quarantine area of Texas along the Mexican border are immersed in coumaphos solution by entering a large swim vat containing 4,000 gallons of coumaphos solution.   The quarantine area is staffed by federal workers on a continual basis. There are approximately 44 swim dip vats in the quarantine area. The dip vat workers are monitored for changes in cholinesterase levels and if their cholinesterase is fall below a set level, then the workers are removed from dipping operations.[5] The USDA use almost one half of the total annual production of coumaphos in the US.

After considering the data presented above, it was determined that all exposure scenarios, except for mixing/loading and applying liquids for dip vat use on cattle, will be short-term exposure duration only (less than seven days). Most of the non-dip vat application of coumaphos is done by a farmer to his own animals, when arthropod pests become a problem.   Cattle dip vat use is also considered an intermediate-term exposure since the quarantine area dip vats in Texas along the Mexican border are staffed on a continual basis as opposed to a farmer just dipping the animals that are on his farm. Mixing/loading and applying liquids for cattle dip vat use may not be considered a chronic exposure since the USDA workers dip only the local US cattle and are removed from dipping operations if their cholinesterase levels reach a level of concern.   However, since there is no quantitative data, such as the number of cattle dipped per day, number of days dipping takes place per year, etc., to determine whether there is a chronic exposure to dip vat workers in quarantine areas, HED requests more information on quarantine dipping practices to clarify the duration of exposure.

Summary of Toxicity Concerns

Acute Toxicology Categories

Table 1 presents the acute toxicity categories for the technical grade as outlined in The HED Chapter of the Reregistration Eligibility Decision Document (RED) for Coumaphos, dated April 21, 1995.[6]

Table 1. Toxicity Categories.

Study Type	Toxicity Category
Acute Oral Toxicity	I
Acute Dermal Toxicity	III
Acute Inhalation Toxicity	II
Primary Eye Irritation	III
Primary Dermal Irritation	IV
Dermal Sensitization	not a sensitizer

Toxicological Endpoints of Concern

The Coumaphos Hazard Identification Assessment Review Document, dated June 25, 1999 indicates that there are toxicological endpoints of concern. Dermal and inhalation endpoints of concern have been identified for short-term and intermediate-term exposure durations.[7] See Table 2 for a summary of the toxicological endpoints and uncertainty factors.

The toxicity endpoints selected for risk assessment are based primarily on cholinesterase inhibition. Coumaphos is classified as a Group E chemical, indicating that it is "Not Likely" to be carcinogenic in humans via relevant routes of exposure. This classification is supported by adequate carcinogenicity studies in rats and mice.[7]

For short-term dermal exposure, the toxic endpoint for short term occupational dermal risk assessment is from a 5 day dermal toxicity study (MRID 44749401) in female rats with a NOAEL of 5 mg/kg based on statistically significant inhibition of brain cholinesterase activity (12%) at 10 mg/kg (LOAEL). The next higher dose (20 mg/kg) produced decreased plasma, red blood cell (RBC) and brain cholinesterase activity. Technical coumaphos was given to the rats. An target margin-of-exposure (MOE) of 100 is required for short-term dermal occupational risk assessment and includes the conventional 100 (10x for interspecies extrapolation and 10x for intraspecies variability).

For intermediate-term dermal exposure, the toxic endpoint for the intermediate-term occupational risk assessment is from a 21 day dermal toxicity study (MRID 42666401) in rats with a NOAEL of 0.5 mg/kg based on inhibition of RBC cholinesterase (24%) in female rats at 1.1 mg/kg. Technical coumaphos was given to the rats. An target margin-of-exposure (MOE) of 100 is required for short-term dermal occupational risk assessment and includes the conventional 100 (10x for interspecies extrapolation and 10x for intraspecies variability).

For short- and intermediate-term inhalation exposure, there were no inhalation studies, so oral toxicity data were used as alternatives to inhalation data in route-to route extrapolation for short term and intermediate term inhalation. The toxic endpoint for short-term inhalation risk assessment is from an acute oral neurotoxicity study in rats (MRID 44544801) with a LOAEL of 2 mg/kg based on statistically significant inhibition of plasma cholinesterase in female rats and RBC cholinesterase in both male and female rats. Technical coumaphos was given to the rats. A NOAEL for cholinesterase inhibition was not achieved. An target margin-of-exposure (MOE) of 300 is required for short-term inhalation occupational risk assessment and includes the conventional 100x and an additional 3x factor for the use of a LOAEL (i.e. lack of a NOAEL in the study). The toxic endpoint for intermediate-term inhalation risk assessment is from a 13 week neurotoxicity study in rats (MRID 00126527) with a LOAEL of 0.2 mg/kg based on statistically significant inhibition of RBC cholinesterase activity in male and female rats . No NOAEL was established. Technical coumaphos was given to the rats. An target margin-of-exposure (MOE) of 300 is required for short term inhalation occupational risk assessment and includes the conventional 100 (10x for interspecies extrapolation and 10x for intraspecies variability) and an additional 3x factor for the use of a LOAEL (i.e. lack of a NOAEL in the study).[7]

Although brain cholinesterase inhibition was the critical effect in the short-/or intermediate- term dermal study and RBC and/or plasma cholinesterase inhibition were critical effects in the oral study selected for the short-/or intermediate-term inhalation exposure, the HIARC recommended that since there is a common toxic endpoint (cholinesterase inhibition) via the oral, dermal and inhalation routes, it is appropriate to **combine** dermal and inhalation exposures for short and intermediate term risk assessments. Chronic endpoints were not selected because coumaphos may not be considered to have exposures of chronic durations.[7]

Since the inhalation target MOE for both the short- and intermediate-term is 300, because of the use of a LOAEL, while the short and intermediate term dermal target MOE remains 100, the dermal and inhalation exposure was combined using an aggregate risk index (ARI). An ARI is normalized to 1. So, the scenarios where dermal and inhalation exposures are combined, the ARI must be equal to or greater than one. Some scenarios do not have inhalation data, because studies lacking inhalation data were used, so inhalation and dermal exposure were not combined. For those scenarios, the target MOE is still 100.

Table 2. Coumaphos Hazard Endpoints and Uncertainty Factors.

Route / Duration	NOAEL (mg/kg/day)	Effect	Study	Uncertainty Factors	Comments
Dermal short-term	5.0	Brain Cholinesterase Inhibition in female rats.	5 Day Dermal Study in Rat	Interspecies: 10x Intraspecies: 10x	
Dermal Intermediate-term	0.5	Red Blood Cell Cholinesterase Inhibition	21-Day Dermal Study in Rats	Interspecies: 10x Intraspecies: 10x	
Inhalation Short-term	2.0 (LOAEL)	Plasma ChE Inhibition in females and RBC ChE Inhibition in males and female rats	Acute Neurotoxicity Study in Rats	Interspecies: 10x Intraspecies: 10x LOAEL: 3x	100 percent absorption assumed.
Inhalation Intermediate-term	0.2 (LOAEL)	Red Blood Cell Cholinesterase Inhibition in rats.	13-Week Dietary Study in Rats	Interspecies: 10x Intraspecies: 10x LOAEL: 3x	100 percent absorption assumed.

OCCUPATIONAL EXPOSURE AND RISKS

Chemical-specific data for assessing human exposures during pesticide handling for all exposure scenarios were not submitted to the Agency in support of the reregistration of coumaphos. It is the policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.[8]

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide regulation, and member companies of the Agricultural Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates)

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (i.e. mixing/loading, applying), formulation type (i.e. dusts), application method (i.e., tractor drawn spreader), and clothing scenarios (i.e., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (i.e., chest upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all “other” distributions. Once selected, the central tendency values for each body part are composited into a “best fit” exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Table 3. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.[9]

Handler Exposures & Assumptions

HED has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with coumaphos. Based on the use patterns of coumaphos, 9 major exposure scenarios were identified: (1a) mixing/loading liquids for high pressure hand wand; (1b) mixing/loading liquids for hydraulic type dip vats; (1c) mixing/loading liquids for swim type dip vats; (1d) mixing/loading liquids for back rubber/oilers; (2) loading dust into bags; (3) applying liquids with a high pressure hand wand; (4) applying dusts with a shaker can; (5) mixing/loading/applying liquids for low pressure handwand; and (6) loading/applying dusts with a mechanical duster. Exposure to the applicator from dip vats use was not assessed because there was no exposure data.

Table 3 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment. Short-term ARIs and MOEs at baseline (developed using PHED Version 1.1 surrogate data) are presented in Table 4. The short-term ARIs and MOEs with additional PPE mitigation are presented in Table 5. The short-term ARIs and MOEs with engineering controls mitigation are presented in Table 6. Intermediate-term ARIs at baseline are presented in Table 7. The intermediate-term ARIs with additional PPE mitigation are presented in Table 8. The intermediate-term ARIs with engineering controls mitigation are presented in Table 9.

The following general assumptions are made:

- Average body weight of an adult handler is 70 kg.
- Average work day interval represents an 8 hour workday
- Calculations of handler scenarios are completed using the application rates on the current coumaphos labels.

- PHED Version 1.1 data were used to estimate exposures for all scenarios.[9]

- Due to a lack of scenario-specific data, HED calculated unit exposure values using generic data from the Pesticide Handler Exposure Database (PHED) and, in lieu of PHED data for a scenario, using protection factors that are applied to represent various risk mitigation options (i.e., the use of PPE). See Table 3 for details.

- PHED unit exposure data from mixing and loading liquids for high pressure hand wands were used for the mixing and loading of liquids for the dip vats. The unit exposures are assumed to be similar. PHED unit exposure data for mixing and loading liquids for high pressure hand wands were also used for the mixing and loading of back rubber/oilers. This is assumed to be an underestimate of exposure since the pesticide is mixed with fuel oil, which can increase dermal absorption.

- The study, Application Exposure to the Home Gardener. (1985),[11] was used to assess the exposure to applicators of dust using a mechanical duster and a shaker can. In the study, home gardeners applied dust to their garden using shaker cans and mechanical dusters. No inhalation data was provided. See the study review section at the end of this chapter for more details. Since the use pattern of the study is different from coumaphos animal dusting, this study is considered for informational purposes only. Data on the actual use of coumaphos dust on animals is requested.

- In the *Reassessment of Operator Exposure and Risk For the Animal Spray and Dip Uses of Coumaphos* report dated June 10, 1997, it was stated that a hydraulic type dip vat is 1,800 gallons and a swim dip vat is 4,000 gallons. The vats are recharged when 25 percent of the liquid is depleted.[12]

- Since dip vats are only completely filled every year or two, this use is assumed to be short-term. For short-term mixer and loader exposure, one person is assumed to mix and load the original dip vat liquid. The dip vat liquid is recharged when the level falls below 25 percent and this is a more frequent event then filling the entire dip vat, so recharging the dip vat is considered an intermediate-term use. For intermediate-term mixer and loader exposure, it is assumed that one person would recharge the vat when is the liquid level falls below 25 percent. Therefore, a person mixing and loading for a hydraulic type dip vat will handle a total of 1,800 gallons/day for the short-term uses and 450 gallons/day for the intermediate-term uses. A person mixing and loading for a swim type dip vat will handle a total of 4,000 gallons/day for the short-term uses and 1,000 gallons/day for the intermediate-term uses.

- Amount handled per day for backrubbers and dusts: 14 gallons for a back rubber/oiler (seven, two gallon back rubbers). 50 animals and 1000 square feet of swine bedding treated with mechanical duster and shaker can. These values are based on HED's best professional judgement.

- The current coumaphos liquid labels restrict the number of animals that can be sprayed per day to 100 at the maximum application rate. It is assumed that one gallon of spray solution would be used per animal. This would result in a maximum of 100 gallons sprayed per day at the lowest level of dilution. The registrant wishes to remove this restriction because of a new short-term dermal endpoint. In order to determine if this restriction can be lifted, both the label restriction rate and the maximum amount that one person could spray in one day will be assessed. For a high pressure hand wand, the rates assessed will be the label restricted rate of 100 gallons per day and the maximum rate that can be sprayed in one day of 1000 gallons. For low pressure hand wands, the rate that will be assessed is the maximum amount that can be sprayed per day of 40 gallons, which is already below the label restriction of 100 gallons per day.

Potential daily dermal exposure is calculated using the following formula:

$$Daily\ Dermal\ Exposure \left(\frac{mg\ ai}{day}\right) = Unit\ Exposure \left(\frac{mg\ ai}{lb\ ai}\right) x\ Use\ Rate \left(\frac{lb\ ai}{gal,\ animal,\ sq.\ ft.,\ day}\right) x\ Daily\ Amount\ Treated \left(\frac{gal,\ animal,\ sq.\ ft.}{day}\right)$$

Potential daily inhalation exposure is calculated using the following formula:

$$Daily\ Inhalation\ Exposure \left(\frac{mg\ ai}{day}\right) = Unit\ Exposure \left(\frac{\mu g\ ai}{lb\ ai}\right) x$$
$$Conversion\ Factor \left(\frac{1 mg}{1{,}000\ \mu g}\right) x\ Use\ Rate \left(\frac{lb\ ai}{gal,\ animal,\ sq.\ ft.,\ day}\right) x\ Daily\ Amount\ Treated \left(\frac{gal,\ animal,\ sq.ft.}{day}\right)$$

The daily dermal and inhalation dose is calculated using a 70 kg body weight for both short-term and intermediate-term exposure as follows:

$$Daily\ Inhalation\ Dose \left(\frac{mg\ ai}{kg/day}\right) = Daily\ Inhalation\ Exposure \left(\frac{mg\ ai}{day}\right) x \left(\frac{1}{Body\ Weight\ (kg)}\right)$$

$$Daily\ Dermal\ Dose \left(\frac{mg\ ai}{kg/day}\right) = Daily\ Dermal\ Exposure \left(\frac{mg\ ai}{day}\right) x \left(\frac{1}{Body\ Weight\ (kg)}\right)$$

Based on the available toxicity data, it is appropriate to combine short-term dermal and inhalation MOEs and Intermediate-term dermal and inhalation MOEs because the effects observed at the NOAEL are identical. The short-term and intermediate-term MOE for dermal exposure were calculated using a NOAEL of 5.0 mg/kg/day and a NOAEL of 0.5 mg/kg/day, respectively. The short-term and intermediate-term MOE for inhalation exposure were calculated using a NOAEL of 2.0 mg/kg/day and 0.2 mg/kg/day.[7]

The inhalation and dermal MOEs were calculated using the following formulas:

$$Dermal\ MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Dermal\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

$$Inhalation\ MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Inhalation\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

Since the target MOE levels were different for dermal and inhalation, 100 and 300 respectively, then an aggregate risk index (ARI) must be used instead of a total MOE. The ARI were calculated using the following formula:

$$ARI = \frac{1}{\left(\frac{1}{\frac{calculated\ dermal\ MOE}{acceptable\ dermal\ MOE}}\right) + \left(\frac{1}{\frac{calculated\ inhalation\ MOE}{acceptable\ inhalation\ MOE}}\right)}$$

Table 3. Occupational Exposure Scenario Descriptions for the Use of Coumaphos

Exposure Scenario (Number)	Data Source	Standard Assumption[a] (8-hr work day)	Comments[b]
Mixer/Loader Descriptors			
Mixing/Loading Liquid Formulations (1a/1b/1c/1d)	PHED V1.1	100 and 1000 gallons for high pressure handwand, 14 gallons for back rubber /oiler (7, 2 gallon back rubbers), 1,800 gallons for hydraulic type dip vat and 4,000 gallons for swim type dip vats (short term). and 450 gallons for hydraulic type dip vat and 1,000 gallons for swim type dip vats (int. term).	**Baseline:** Hand, dermal, and inhalation data are AB grades. Hand = 72 to 122 replicates; dermal = 53 replicates; and inhalation = 85 replicates. High confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing, and an 80% protection factor to account for the use of a dust/mist respirator, respectively. Hand data are AB grades, with 59 replicates. High confidence in hand/dermal data. **Engineering Controls:** Not feasible for this scenario.
Loading dusts (2)	no data	no data	no data
Applicator Exposure			
Applying liquids with a high pressure hand wand (3)	PHED V1.1	100 and 1000 gallons	**Baseline:** Hand, dermal, and inhalation data are all grades. Hand = 2 replicates; dermal = 9 to 11 replicates; and inhalation = 11 replicates. Low confidence in hand/dermal and inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** Hand/dermal data are all grades. The same inhalation data are used as for the baseline coupled with an 80% protection factor to account for the use of a dust/mist respirator. Hand = 9 replicates and dermal = 9 to 11 replicates. Low confidence in hand/dermal data. **Engineering Controls:** Not feasible for this scenario.
Applying dusts with shaker can (4)	Study	50 animals and 1,000 square feet	Bode, William M. and Kurtz, David A., <u>Application Exposure to the Home Gardener.</u> American Chemical Society Symposium Series 273, Washington, DC. (1985). [11]
Mixer/Loader/Applicator Exposure			
Mixing/loading/applying liquids with a low pressure handwand (5)	PHED V1.1	40 gallons	**Baseline:** Hand data are All grades, dermal are ABC grades, and inhalation data are ABC grades. Hand = 70 replicates; dermal = 9 to 80 replicates; and inhalation = 80 replicates. Low confidence in hand/dermal data, and medium confidence in inhalation data. No protection factor was needed to define the unit exposure value. **PPE:** The same dermal and inhalation data are used as for the baseline coupled with a 50% protection factor to account for an additional layer of clothing, and an 80% protection factor to account for the use of a dust/mist respirator, respectively. Hand data are ABC grades, with 10 replicates. Low confidence in hand/dermal data. **Engineering Controls:** Not feasible for this scenario.
Loading/applying dusts with a mechanical duster (6)	study	50 animals and 1000 square feet	Bode, William M. and Kurtz, David A., <u>Application Exposure to the Home Gardener.</u> American Chemical Society Symposium Series 273, Washington, DC. (1985). [11]

a Standard Assumptions based on an 8-hour work day as estimated by EPA. BEAD data were not available.

b "Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Acceptable grades are matrices with grades A and B data. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates
Medium = grades A, B, and C and 15 or more replicates
Low = grades A, B, C, D, and E <u>or</u> any combination of grades with less than 15 replicates

Table 4. Occupational Short-term Dermal and Inhalation Exposure to Coumaphos and Risks at Baseline.

Exposure Scenario (Scenario #)	Dermal Unit Exposure (mg/lb ai)[a]	Inhalation Unit Exposure (Fg/lb ai)[b]	Application Rate (lb ai/ animal, gallon, sq. ft., or day)[c]	Daily Animals Treated or Amount Used[d]	Animal (cattle includes both dairy and beef)	Daily Dermal Dose (mg/kg/ day)[e]	Daily Inhalation Dose (mg/kg/ day)[f]	Dermal MOE[g]	Inhalation MOE[h]	ARI[j]
Mixer/Loader Exposure and Dose Levels										
Mixing/loading liquids for high pressure handwand(1a)	2.9	1.2	21 lbs ai/1000 gal	100 gal/day	cattle/horse	0.087	0.00004	60	56,000	0.57
			5 lbs ai/1000 gal	100 gal/day	swine	0.021	0.00001	240	230,000	2.4
			21 lbs ai/1000 gal	1000 gal/day	cattle/horse	0.87	0.00036	6	5,600	0.057
			5 lbs ai/1000 gal	1000 gal/day	swine	0.21	0.00009	24	23,000	0.24
Mixing/loading liquids for hydraulic type dip vats (1b)			25 lbs ai/1000 gal	1,800 gal/day	cattle	2	0.00077	3	2,600	0.027
Mixing/loading liquids for swim dip vats (1c)			25 lbs ai/1000 gal	4,000 gal/day	cattle	4	0.0017	1	1,200	0.012
Mixing/loading liquids for back oiler/ rubbers(1d)			76 lbs ai/1000 gal	14 gal/day	cattle	0.044	0.00002	110	110,000	1.1
Loading dusts into dust bags (2)	no data	no data	0.000625lbs ai/day	N/A	cattle	no data	no data	no data	no data	no data
Applicator Exposure and Dose Levels										
Applying liquids for high pressure hand wand (3)	1.8	79	21 lbs ai/1000 gal	100 gal/day	cattle/horse	0.054	0.0024	93	840	0.70
			5 lbs ai/1000 gal	100 gal/day	swine	0.013	0.00056	390	3,500	2.9
			21 lbs ai/1000 gal	1000 gal/day	cattle/horse	0.54	0.024	9	84	0.069
			5 lbs ai/1000 gal	1000 gal/day	swine	0.13	0.0056	39	350	0.29
Applying dusts with a shaker can (4)	203	no data	0.0013 lbs ai/animal	50 animals /day	cattle/horse	0.19	no data	27	no data	N/A
			0.000625 lbs ai/animal	50 animals /day	swine	0.09	no data	55	no data	N/A
			0.042 lbs ai/1000 sq. ft.	1,000 sq. ft./day	swine bedding	0.12	no data	41	no data	N/A
Mixer/Loader/Applicator Exposure and Dose Levels										
Mixing/loading/applying liquids with a low pressure hand wand (5)	100	30	21 lbs ai/1000 gal	40 gal/day	cattle/horse	1.2	0.00036	4	5600	0.042
			5 lbs ai/1000 gal	40 gal/day	swine	0.28	0.00009	18	23000	0.17
Loading/applying dust with a mechanical duster (6)	203	no data	0.0013 lbs ai/animal	50 animals /day	cattle/horse	0.19	no data	27	no data	N/A
			0.000625 lbs ai/animal	50 animals /day	swine	0.091	no data	55	no data	N/A
			0.042 lbs ai/1000 sq. ft	1000 sq. ft/day	swine bedding	0.12	no data	41	no data	N/A

Footnotes

a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading.
b Baseline inhalation exposure represents no respirator.

c Application rates are maximum application rates for specified animals from the coumaphos labels.
d Daily animals treated or amounts used are EPA HED estimates on the amount that could be applied or number of animals that could be treated in one day.
e Daily dermal dose (mg/day) =(Dermal Unit Exposure (mg/lb ai) * Application rate (lb ai/ animal, gallons, sq. ft., or day) * Amount treated (animal, gallons, or sq. ft./day))/Body Weight (70 kg).
f Daily inhalation dose (mg/day) =(Inhalation Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion factor * Application rate (lb ai/animal, gallons, sq. ft., or day) * Acres treated (animal, gallons, sq. ft. /day))/Body Weight (70 kg)..
g Short-term Dermal MOE = Short-term Dermal NOAEL (5 mg/kg/day)/Short-term Dermal Dose (mg/kg/day).
h Short-term Inhalation MOE = Short-term Inhalation NOAEL (2 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
i Short-term ARI = 1/((1/(calculated short-term dermal MOE/target short-term MOE (100)) + (1/(calculated short-term inhalation MOE/target short-term MOE (300))). Target level is 1.
N/A = Not Applicable= amount used per day not necessary for calculation, an ARI cannot be identified since there is no inhalation data.

Table 5. Occupational Short-term Dermal and Inhalation Exposure to Coumaphos and Risks at Additional PPE.

Exposure Scenario (Scenario #)	Animal (cattle includes both dairy and beef)	Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Dermal MOE[d]	Inhalation MOE[e]	ARI[f]
Mixer/Loader Exposure and Dose Levels							
Mixing/loading liquids for high pressure handwand (1a)	100 cattle/horse	0.17	0.00051	0.00001	9,800	280,000	87
	100 swine		0.00012	0.0000017	-	-	-
	1,000 cattle/horse		0.0051	0.00007	980	28,000	8.9
	1,000 swine		0.0012	0.00002	4,100	120,000	37
Mixing/loading liquids for hydraulic type dip vats (1b)	cattle		0.011	0.00015	460	13,000	4
Mixing/loading liquids for swim dip vats (1c)	cattle		0.024	0.00034	210	5,800	1.9
Mixing/loading liquids for back oiler /rubbers(1d)	cattle		0.00026	0.0000036	-	-	-
Loading dusts into dust bags (2)	cattle	no data	no data	no data	no data	no data	no data
Applicator Exposure and Dose Levels							
Applying liquids for high pressure hand wand (3)	100 cattle/horse	0.36	0.011	0.00047	460	4,200	3.5
	100 swine		0.0026	0.00011	-	-	-
	1,000 cattle/horse		0.11	0.0047	46	420	0.35
	1,000 swine		0.026	0.0011	190	1800	1.5
Applying dusts with a shaker can (4)	cattle/horse	110	0.10	no data	48	no data	N/A
	swine		0.05	no data	100	no data	N/A
	swine bedding		0.07	no data	74	no data	N/A
Mixer/Loader/Applicator Exposures and Doses							
Mixing/loading/applying liquids with a low pressure hand wand (5)	cattle/horse	0.37	0.0044	0.00007	1100	28000	10
	swine		0.001	0.00002	4700	120000	42
Loading/applying dusts with a mechanical duster (6)	cattle/horse	110	0.10	no data	48	no data	N/A
	swine		0.05	no data	100	no data	N/A
	swine bedding		0.07	no data	74	no data	N/A

Footnotes

a Additional PPE for all dermal scenarios includes double layer of clothing, coveralls and chemically resistant apron , (50% Protection Factor) and chemical resistant gloves (90% Protection Factor).
b Short- term Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (70 kg))
c Short-term Daily Inhalation Dose = (Short-term Inhalation Dose at baseline (Table 3))/5 (80% protection factor for dust/mist respirator)
d Short-term Dermal MOE = Short-term Dermal NOAEL (5 mg/kg/day)/ Short-term Dermal Dose (mg/kg/day).
e Short-term Inhalation MOE = Short-term Inhalation NOAEL (2 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
f Short -Term ARI = 1/((1/(calculated short-term dermal MOE/target short-term MOE (100)) + (1/(calculated short-term inhalation MOE/target short-term MOE (300))). Target level is 1.
N/A = Not Applicable= an ARI cannot be identified since there is no inhalation data.

Table 6. Occupational Short-term Dermal and Inhalation Exposure to Coumaphos and Risks with Engineering Controls.

Exposure Scenario (Scenario #)	Animal (cattle includes both dairy and beef)	Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Unit Inhalation Exposure[c] (mg/lb ai)	Daily Inhalation Dose[c] (mg/kg/day)	Short-term		
						Dermal MOE[d]	Inhalation MOE[e]	ARI[f]
Mixer/Loader Exposure and Dose Levels								
Mixing/loading liquids for high pressure handwand (1a)	100 cattle/horse	0.0086	0.00026	0.083	0.0000025	-	-	-
	100 swine		0.00006		0.00000059	-	-	-
	1,000 cattle/horse		0.0026		0.00002	-	-	-
	1,000 swine		0.00061		0.00001	-	-	-
Mixing/loading liquids for hydraulic type dip vats (1b)	cattle		0.0055		0.00005	-	-	-
Mixing/loading liquids for swim dip vats (1c)	cattle		0.013		0.00012	-	-	-
Mixing/loading liquids for back oiler /rubbers(1d)	cattle		N/A		N/A	N/A	N/A	N/A
Loading dusts into dust bags (2)	cattle	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Applicator Exposure and Dose Levels								
Applying liquids for high pressure hand wand (3)	100 cattle/horse	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	100 swine		N/A		N/A	N/A	N/A	N/A
	1,000 cattle/horse		N/A		N/A	N/A	N/A	N/A
	1,000 swine		N/A		N/A	N/A	N/A	N/A
Applying dusts with a shaker can (4)	cattle/horse	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	swine		N/A		N/A	N/A	N/A	N/A
	swine bedding		N/A		N/A	N/A	N/A	N/A
Mixer/Loader/Applicator Exposures and Doses								
Mixing/loading/applying liquids with a low pressure hand wand (5)	cattle/horse	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	swine		N/A		N/A	N/A	N/A	N/A
Loading/applying dusts with a mechanical duster (6)	cattle/horse	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	swine		N/A		N/A	N/A	N/A	N/A
	swine bedding		N/A		N/A	N/A	N/A	N/A

Footnotes

a Scenario Number — Engineering Controls
1a / 1b/1c — Closed mixing / loading (98% protection factor), single layer clothing, chemical resistant gloves.

b Short- term Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (70 kg))

c Short-term Daily Inhalation Dose = ((Inhalation Unit Exposure (Fg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)*(1 mg/1000 Fg)) / Body Weight (70 kg))

d Short-term Dermal MOE = Short-term Dermal NOAEL (5 mg/kg/day)/ Short-term Dermal Dose (mg/kg/day).

e Short-term Inhalation MOE = Short-term Inhalation NOAEL (2 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

f Short -Term ARI = 1/((1/(calculated short-term dermal MOE/target short-term MOE (100)) + (1/(calculated short-term inhalation MOE/target short-term MOE (300))). Target level is 1.

N/A = Not Applicable= an ARI cannot be identified since there is no inhalation data.

Table 7. Occupational Intermediate-term Dermal and Inhalation Exposure to Coumaphos and Risks at Baseline.

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (Fg/lb ai)[b]	Application Rate (lb ai/ animal, gallon, sq. ft., or day)[c]	Daily Animals Treated or Amount Used[d]	Animal (cattle includes both dairy and beef)	Daily Dermal Dose (mg/kg / day)[e]	Daily Inhalation Dose (mg/kg/ day)[f]	Intermediate-term Baseline Dermal MOE[g]	Intermediate-term Baseline Inhalation MOE[h]	Intermediate-term ARI[j]
Mixer/Loader Exposure and Dose Levels										
Mixing/loading liquids for hydraulic type dip vats (1b)	2.9	1.2	25 lbs ai/1000 gal	450 gal/day	cattle	0.47	0.00019	1	1,000	0.011
Mixing/loading liquids for swim dip vats (1c)			25 lbs ai/1000 gal	1,000 gal/day	cattle	1.0	0.00043	0.48	470	0.0048

Footnotes

a Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading.
b Baseline inhalation exposure represents no respirator.
c Application rates are maximum application rates for specified animals from the coumaphos labels.
d Daily animals treated or amounts used are EPA HED estimates on the amount that could be applied or number of animals that could be treated in one day.
e Daily dermal dose (mg/day) =(Dermal Unit Exposure (mg/lb ai) * Application rate (lb ai/ animal, gallons, sq. ft., or day) * Amount treated (animal, gallons, or sq. ft./day))/Body Weight (70 kg).
f Daily inhalation dose (mg/day) =(Inhalation Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion factor * Application rate (lb ai/animal, gallons, sq. ft., or day) * Acres treated (animal, gallons, sq. ft. /day))/Body Weight (70 kg)..
g Intermediate-term Dermal MOE = Intermediate-term Dermal NOAEL (0.5 mg/kg/day)/Intermediate-term Dermal Dose (mg/kg/day).
h Intermediate-term Inhalation MOE = Intermediate-term Inhalation NOAEL (0.2 mg/kg/day)/Intermediate-term Daily Inhalation Dose (mg/kg/day).
i Intermediate-term ARI = 1/((1/(calculated int-term dermal MOE/target int-term MOE (100)) + (1/(calculated int-term inhalation MOE/target int-term MOE (300))). Target level is 1.

Table 8. Occupational Intermediate-term Dermal and Inhalation Exposure to Coumaphos and Risks at Additional PPE.

Exposure Scenario (Scenario #)	Animal (cattle includes both dairy and beef)	Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Intermediate-term Dermal MOE[d]	Intermediate-term Inhalation MOE[e]	Intermediate-term ARI[f]
Mixer/Loader Exposure and Dose Levels							
Mixing/loading liquids for hydraulic type dip vats (1b)	cattle	0.17	0.0027	0.00004	180	5,200	1.7
Mixing/loading liquids for swim dip vats (1c)	cattle		0.0061	0.00009	82	2,300	0.74

Footnotes

a Additional PPE for all dermal scenarios includes double layer of clothing, coveralls and chemically resistant apron , (50% Protection Factor) and chemical resistant gloves (90% Protection Factor).
b Intermediate- term Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (70 kg))
c Intermediate-term Daily Inhalation Dose = (Short-term Inhalation Dose at baseline (Table 3))/5 (80% protection factor for dust/mist respirator)
d Intermediate-term Dermal MOE =Intermediate-term Dermal NOAEL (0.5 mg/kg/day)/ Intermediate-term Dermal Dose (mg/kg/day).
e Intermediate-term Inhalation MOE = Intermediate-term Inhalation NOAEL (0.2 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).
f Intermediate-Term ARI =1/((1/(calculated short-term dermal MOE/target short-term MOE (100)) + (1/(calculated short-term inhalation MOE/target short-term MOE (300))). Target level is 1.

Table 9. Occupational Intermediate-term Dermal and Inhalation Exposure to Coumaphos and Risk with Engineering Controls.

Exposure Scenario (Scenario #)	Animal (cattle includes both dairy and beef)	Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Unit Inhalation Exposure[a] (mg/lb ai)	Daily Inhalation Dose[c] (mg/kg/day)	Intermediate-term		
						Dermal MOE[d]	Inhalation MOE[e]	ARI[f]
Mixer/Loader Exposure and Dose Levels								
Mixing/loading liquids for hydraulic type dip vats (1b)	cattle	0.086	0.0014	0.083	0.00001	-	-	-
Mixing/loading liquids for swim dip vats (1c)	cattle		0.0031		0.00003	160	6,700	1.5

Footnotes

a Scenario Number — Engineering Controls

1a / 1b/1c — Closed mixing / loading (98% protection factor), single layer clothing, chemical resistant gloves.

b Intermediate- term Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (70 kg))

c Intermediate-term Daily Inhalation Dose = ((Inhalation Unit Exposure (Fg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)*(1 mg/1000 Fg)) / Body Weight (70 kg))

d Intermediate-term Dermal MOE = Short-term Dermal NOAEL (5 mg/kg/day)/ Short-term Dermal Dose (mg/kg/day).

e Intermediate-term Inhalation MOE = Short-term Inhalation NOAEL (2 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

f Intermediate -Term ARI = 1/((1/(calculated short-term dermal MOE/target short-term MOE (100)) + (1/(calculated int-term inhalation MOE/target int-term MOE (300))). Target level is 1.

Summary of Risk Concerns for Occupational Handlers

The short-term dermal and inhalation NOAELs were both based on cholinesterase inhibition. As a result, the MOEs were combined in this risk assessment, **except** where there was no inhalation data, which occurred when studies lacking inhalation data were used. Inhalation exposure is considered to be significantly lower than dermal exposure since the vapor pressure of coumaphos is low (9.7 x 10^{-8} torr). For dip vat use on cattle, the intermediate-term dermal and inhalation NOAELs were both based on cholinesterase inhibition, so the MOEs were combined. Since the dermal and inhalation target MOEs are different, 100 and 300 respectively, an aggregate risk index (ARI) was calculated in place of a total MOE. To be acceptable, the ARI must be equal to or greater than 1. For scenarios where there were no inhalation data, and thus the dermal and inhalation MOEs were not aggregated, the target MOE remains 100.

Baseline Level

All calculated short-term ARIs were **less than** 1 at the **baseline** level for all the assessed exposure scenarios **except** for the following:

- (1a) Mixing/loading liquids for high pressure handwand at the application rate for swine of 5 lbs ai per 1000 gallons and use rate of 100 gallons per day.

- (1d) Mixing/loading liquids for back oiler/rubbers.

- (3) Applying liquids for high pressure hand wands at the application rate for swine of 5 lbs ai per 1000 gallons and use rate of 100 gallons per day.

The calculations of short-term dermal risk for scenarios that lack inhalation data, indicate that dermal MOEs are **less than** 100 at the **baseline** level for the all the assessed exposure scenarios.

All calculated intermediate-term ARIs were **less than** 1 at the **baseline** level for all exposure scenarios.

Additional PPE

The calculations of short-term total risk indicate that the ARIs are **more than** 1 at the **additional PPE** level for all assessed exposure scenarios **except** the following:

- (3) Applying liquids for high pressure hand wand at the application rate for cattle and horses and the use rate of 1,000 gallons/day (not able to mitigate with engineering controls).

All calculated short-term dermal MOEs for scenarios that lack inhalation data were **more than** 100 at the **additional PPE** level for all assessed exposure scenarios **except** for the following:

- (4) Applying dusts with a shaker can on cattle, horses, and swine bedding (not able to mitigate with engineering controls).

- (6) Loading/applying dusts with a mechanical duster on cattle, horses, and swine bedding (not able to mitigate with engineering controls).

All calculated intermediate-term ARIs were **more than** 1 at the **additional PPE** level for the assessed scenarios except the following:

- (1c) Mixing/Loading for swim type dip vats.

Engineering Controls

The calculations of short-term total risk indicate that the ARIs are **more than** 1 at the **engineering control** level for all assessed exposure scenarios.

All calculated intermediate-term ARIs were **more than** 1 at the **engineering control** level for the assessed scenarios.

Data Gaps

There were no available data to assess exposure to the following exposure scenarios:

- (2) Loading dusts into bags.

- (4) Inhalation exposure from applying dusts with a shaker can.

- (6) Inhalation exposure form loading/applying dusts with a mechanical duster.

Post Application:

No registered uses of coumaphos fall under the Worker Protection Standard (WPS). The EPA has established the following for all non-WPS occupational uses of coumaphos end use products, "Do not contact treated animals until sprays have dried and dusts have settled on the coat."

HED has determined that there is likely to be minimal exposure to people contacting treated animals immediately after application is complete. No exposure data are available to assess risk from such contact. HED has determined that the amount of exposure is likely to be substantially lower that the exposure to handlers; therefore, post-application exposure was not assessed.

Study Review

Applicator Exposure to the Home Gardener. (1985).[11] In this study, exposure to home gardeners applying dusts was measured using carbaryl as a model pesticide. In 15 minutes, volunteers applied 10 grams of active ingredient in dusts. Insecticide deposits on each person were sampled with 10 cm square gauze pads attached with masking tape to selected locations on white Tyvek coveralls and/or directly on the bodies of the applicators. The pads were located on the face (mask), shoulder tops, upper back, upper chest (right and left), mid forearms (right and left), hand (right and left), mid thigh (right and left), cuff (right and left), shoe vamp (right and left), and foot (right and left). The foot and shoe data was not used. Dermal exposure to the hands was measured using a hand rinse with 200 ml of 0.03% NaOH in ethanol. The 5% dust was applied by either a shaker can or a mechanical duster. The shaker can was used in two instances, thus most of the applications were made with the mechanical duster. Applicator exposure included filling the device prior to application and emptying it following application. The data will be used for the scenario of loading/applying dust with mechanical duster and applying dusts with shaker can. Each volunteer was given 15 minutes for the application of the pesticide to the garden and were told to follow label instructions. A total of 24 replicates, including filling, applying and emptying the equipment, were monitored for each formulation.

The pads were extracted with methanol containing 0.03 percent NaOH. Samples were analyzed within 6 hours of collection to minimize breakdown of carbaryl. Recoveries from 6 gauze pads, fortified in the field at levels of 10 Fg and 50 Fg, were 101 and 98 percent recovery, respectively. Similar recoveries from ethanol solutions spiked at 50 and 200 Fg levels were 144 and 189 percent, respectively. Inhalation exposure was not measured.

The dermal unit exposure was calculated by taking each body section at the no protection level and reducing it by its respective protection factor. To obtain baseline exposure, the shoulders, back, chest (right and left), forearms (right and left), thighs (right and left), and lower leg (right and left) were reduced by a 50 percent protection factor for a single layer of clothing consisting of long pants and long sleeves. The exposures were then converted from mg/15 minutes to mg/lb ai, using 10 grams of active ingredient applied during the 15 minute period. The converted baseline exposures were than summed to calculate a total exposure. For the additional PPE level of exposure, the baseline levels of exposure for the shoulders, back, chest (right and left), forearms (right and left), thighs (right and left), and lower leg (right and left) were again reduced by the 50 percent protection factor to account for the coveralls. The hand data was also reduced by 90 percent to account for wearing gloves. The data was summed to calculate a total exposure. Inhalation data were not collected. This dermal unit exposure data at baseline and additional PPE levels was used to assess loading and applying dusts using a mechanical spreader and applying dusts using a shaker can. The data was used for a unit dermal exposure to a shaker can even though there were only two shaker can replicates and 22 mechanical duster replicates out of 24 replicates, because there was no other data available on the unit dermal exposure to shaker cans. HED considers exposure to be application method specific and not chemical specific, so it is assumed that the exposure for applying dusts to animals using a shaker can and mechanical duster is similar to applying dusts to the garden with a shaker can. The baseline dermal unit exposure value was calculated to be 203 mg/lb ai handled and additional PPE dermal unit exposure value was calculated to be112 mg/lb ai handled.

Occupational Hygiene Assessment of Sheep Dipping Practices and Processes. October 1993, MRID 442529-01.[13] This is a collaborative Health and Safety Executive (HSE) and the Institute of Occupational Medicine (IOM) study of sheep dipping practices submitted by the registrant in support of coumaphos. It was conducted in 1992 using occupational hygiene evaluation of the five most common sheep dipping practices, mobile, long swim, short swim, circular with an island, and circular. Airborne concentrations of the OP insecticide diazinon measured during these studies were less than the analytical detection limit of the method (<0.01 mg/m^3). The location of the air sampler was not described in the study.

Fourteen different sheep dipping operations were studied which involved 38 individuals. The human metabolism and excretion of the active ingredient of sheep dip under the conditions observed were assessed. Samples of blood obtained from participating workers were analyzed for red blood cell and plasma cholinesterase activity. Corresponding urine samples were analyzed for the metabolites of diazinon; diethyl phosphate (DEP) and diethylthiophosphate (DETP). Photographic records and video recordings were obtained for all visits and were used to assist in the descriptions of working methods and the interpretation of results.

Four occupational groups were used in the study, the paddler who maneuvers the sheep in the bath, plunges them under and ensures a safe exit, the chucker who puts sheep in the bath, the helper who rounds up the sheep before dipping and returns them to pasture after dipping, and the contractor who owns a mobile dipper and helps the paddler and chucker. Some workers were visibility soaked, especially paddlers and chuckers, while some handlers were barely splashed. A number farms had splash control devices, such as splash guards and remote control gates. It was not possible to assess directly exposure from the contact with contaminated surfaces or concentrated dip although the individuals who handled concentrate had significantly higher concentrations of urinary metabolites. The levels of diazinon metabolites in the urine were low. Metabolites were detected in the pre-dipping urine samples of 15 out of 36 workers on farms were diazinon was used. This may have been a result of prior diazinon use. There was little change in the amount of diazinon metabolites detected from pre to post dipping. Sixteen out of 36 showed no increase, with the reminder ranging from 1 to 146 nmol/mmol creatinine. The amount of metabolite present in the next morning samples adjusted for pre-dipping levels, ranged from 0 to 151 nmol/mmol creatinine, the mean being 22.6 and the median being 16 nmol/mmol creatinine.

The largest decrease in plasma cholinesterase activity for a worker was 14 percent, which was accompanied by a decrease in red cell cholinesterase activity of 2 percent. The largest decrease for red blood cell cholinesterase was 10 percent.

Field trials of HSE's flourescent imaging technique for assessing skin contamination were performed at six farms. Contamination was observed, but the quantitative estimates maybe a little low because of technical problems with the method. The flourescent imaging data was not used because there was no leg data reported, an area of high expose when dipping.

The biomonitoring data cannot be used because pharmokinetic data was not supplied to show that diazinon is absorbed through the skin at the same rate as coumaphos. Without this information, the biomonitoring data may under or over estimate exposure to coumaphos from the same activity. Also, individual worker biomonitoring data was not supplied with the study. This is needed to calculate more accurately the exposure to coumaphos through the use of biomonitoring data.

Occupational Hygiene Assessment of Exposure to Insecticide and the Effectiveness of Protective Clothing During Sheep Dipping Operations. August 1996. MRID 442529-02.[10] This study is on sheep dipping that took place in 1992 and 1993. The main study was took place at twelve farms during two phases. Contamination and penetration of the protective clothing, consisting of PVC or other waterproof fabric with diazinon or propetamphos, two common chemicals used in dipping sheep, was assessed using garment samplers. These absorbent coverall suits were worn outside protective clothing on one day and inside protective clothing on another day. At the end of each dipping session the garment samples were sectioned into 6 pieces and stabilized before removal to the laboratory for analysis. Penetration of insecticide through the protective clothing was generally minimal with protection factor ranging from 4 to 1000. Most of the penetration was detected on the lower arms and legs.

The data from the absorbent coverall suits worn outside the body was used in this assessment to determine the unit dermal exposure for applying dip to sheep and goats. The outside of the suit data (no protection) was reduced by a 50 percent protection factor to obtain baseline level, which consists of long pants, long sleeves. No hand data was provided, so the unit exposure may underestimate exposure to the applicator. The an additional PPE level of protection was calculated by reducing the baseline unit exposure by a 50 percent protection factor. The additional PPE level of protection consists of long pants, long sleeve and coveralls. Since hand data was no provided and the hands are exposed significantly during dipping, gloves will be added to the additional PPE level of protection. The amount of ai handled was assumed to be the amount of active ingredient in the concentrate added during the day. No inhalation data was provided. The baseline dermal unit exposure was calculated to be 10.1 mg/lb ai handled and the additional PPE unit exposure was calculated to be 5.1 mg/lb ai handled. It was assumed that the exposure to dipping sheep is similar to the exposure to dipping goats.

During the second phase of the study 32 individuals provided two samples of blood, per and post dipping, and three urine samples, pre, post dipping and the next morning, for cholinesterase activity determination and urinary metabolite analysis respectively. Half of the farms studied used dip based on diazinon and the remaining six farms used chlorfenvinphos-based dips.

Concentration of the metabolites of diazinon, diethyl phosphate (DEP) and diethylthiophosphate (DETP), ranged from 1 to 227 nmole/mmole creatine. No urinary metabolites of chlorfenvinphos were detected in the urine in 10 of the 15 workers, even after dipping. The highest concentration was 47 nmol/mol creatine, with the rest ranging from 20 to 35 nmol/mmol creatine. The biomonitoring data cannot be used because pharmokinetic data was not supplied to show that diazinon and chlorfenvinphos are absorbed through the skin at the same rate as coumaphos. Without this information, the biomonitoring data may under or over estimate exposure to coumaphos from the same activity. Also, individual biomonitoring data was not supplied with the study. This is needed to calculate more accurately the exposure to coumaphos through biomonitoring data.

The subjects experienced a decrease in plasma of less than 15 percent or a decrease in erythrocyte of less than 10 percent cholinesterase activity. The highest decrease in plasma cholinesterase activity was 9 percent.

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